Supreme Court, U. S.
FILED
FEB 7 1979
MICHAEL RODAK, JR., CLERK

No. 78-935

In the Supreme Court of the United States

OCTOBER TERM, 1978

MARVIN W. JOHNSON, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

WADE H. MCCREE, JR.
Solicitor General

JOHN H. SHENEFIELD
Assistant Attorney General

BARRY GROSSMAN
J. PATRICK GLYNN
WILLIAM D. COSTON
Attorneys
Department of Justice
Washington, D.C. 20530

RICHARD M. COOPER
Chief Counsel

ROBERT P. BRADY
Attorney
Food and Drug Administration
Rockville, Maryland 20852

In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-935

MARVIN W. JOHNSON, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

---

1. Petitioner was, during the indictment period, the secretary of the Southwestern Plasma Center, Inc., a commercial corporation in Florida that obtained human blood plasma, separated it into Source Plasma (Human) and Fresh Human Serum, and then sold those products (Pet. App. 1a; Tr. 346-347, 3134-3136, 3146).[1] Both Source Plasma (Human)

[1] "Pet. App." refers to the Appendix to the petition for a writ of certiorari. "Tr." refers to the official transcript of the trial in the United States District Court for the Middle Dis-

and Fresh Human Serum were drugs, as defined in section 201 of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. 321(g)(1)(B), and subject to the "current good manufacturing practice" requirements of Section 501 of that Act, 21 U.S.C. 351(a)(2)(B). The products were also "biological products" regulated under the Public Health Service Act, to be prepared in compliance with officially promulgated safety, purity, and potency standards. 42 U.S.C. 262(a) and (d).

To implement the drug manufacturing provisions of the Federal Food, Drug, and Cosmetic Act, the FDA promulgated regulations for use throughout the drug industry detailing good manufacturing practice. 28 Fed. Reg. 6385 (June 20, 1963), as amended 32 Fed. Reg. 15109 (Nov. 1, 1967), adopting 21 C.F.R. 133 *et seq.* (now 21 C.F.R. 210 *et seq.*). The regulations required manufacturers to insure, through their facilities, equipment, personnel, and drug components, that the drug has the safety, identity, strength, quality and purity it purports to possess. 21 C.F.R. 133.3-133.6 (now 21 C.F.R. 211.20, 211.30, 211.10 and 211.42). By 1973, the FDA had adopted more specific regulations for the procurement and handling of biological products, including Source

---

trict of Florida, presently lodged with the court of appeals. "Tr.*" refers to the United States' copy of the transcript. The court reporter made one official transcript and several copies, but misnumbered the pages of all the copies. We regret that this memorandum refers to two differently paginated transcripts, but we do not have access to the official transcript for the additional references not included in our court of appeals briefs.

Plasma (Human) and Fresh Human Serum. 38 Fed. Reg. 32048 (November 20, 1973), adopting 21 C.F.R. 600, 610, and 640. These regulations required that every donation of Source Plasma (Human) or Fresh Human Serum be tested for hepatitis, 21 C.F.R. 610.40, and that every first-time donor of Source Plasma (Human) be given a medical examination by a qualified physician. 21 C.F.R. 640.63.

2. In 1976, a grand jury for the Middle District of Florida indicted petitioner, four other individuals, and the Southwestern Plasma Center on sixteen counts for various offenses committed from August 1973 to January 1975 in collecting, manufacturing, storing and shipping plasma and plasma products. The eleven charges ultimately pursued against petitioner consisted of (1) a conspiracy to violate the federal drug and false statement laws, in violation of 18 U.S.C. 371; (2) the making of a false statement in violation of 18 U.S.C. 1001; (3) two violations of Section 351 of the Public Health Service Act, 42 U.S.C. 262, by false labeling of containers of blood components; (4) three violations of Title 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(a), by the introduction of misbranded drugs into interstate commerce; and (5) four violations of Title 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(a), by the introduction of adulterated drugs into interstate commerce. The three misbranded drug charges alleged that the defendants placed labels on plasma and serum samples falsely stating that they were non-reactive to hepatitis. The four adulterated drug charges alleged that three

plasma samples and one serum sample were adulterated because they were not manufactured in compliance with current good manufacturing practice, 21 U.S.C. 351(a)(2)(B), and because of the presence of hepatitis, 21 U.S.C. 351(c).

At trial, the prosecution proved that certain unqualified Human Source Plasma donors were allowed to donate under inactive donors' names (Tr. 1075-1079, 1157-1159, 1455-1458). Petitioner signed forms stating he had physically examined donors, when in fact he had not (Tr. 801-802, 928-929, 1076, 1227-1232, 1423-1429). The Center's employees falsified and invented donor records (Tr. 1461-1468, 1779). Leftover parts of donors' samples were occasionally pooled into one plasma unit and attributed to an inactive or a rejected donor (Tr. 1066-1070*). Plasma testing positive for hepatitis was reported as destroyed but was in fact stored with healthy plasma and then shipped under a label asserting a negative reaction to hepatitis (Tr. 2295-2298, 2336-2342, 3258-3263, 3328-3336). Serum that had tested positive for hepatitis was shipped with the representation that it had tested negatively (Tr. 2384, 2622-2623, 2987-2988).

The prosecution's twenty-sixth witness was Dr. Sam T. Gibson, an expert in plasmapheresis and familiar with the industry's practices during the indictment period (Tr. 2750-2751*). After preliminary questioning, Dr. Gibson responded to nine questions concerning the safety, identity, strength, quality and purity of products manufactured by a plasmapheresis firm (Tr. 2758-2772*). Dr. Gibson stated that, in his

opinion, a plasma donor should be examined by a physician prior to his first donation to insure the safety of both the donor and his product (Tr. 2764*). Each sample should be tested for hepatitis and accurate donor and testing records should be maintained in order to trace any contamination (Tr. 2759*, 2768-2769*). At petitioner's insistence, Dr. Gibson did not use the phrase "good manufacturing practice," and was not permitted to refer to the FDA's regulations (Tr. 2723-2724*, 2736-2737*). His personal opinions comported with the two sets of FDA regulations.[2]

In the closing instructions to the jury, the court observed that, with respect to petitioner, only the four adulteration counts involved the good manufacturing practice of the plasmapheresis industry (Tr. 4200*). The court recited the FDA regulations and

---

[2] Dr. Gibson testified that any first time donor of plasma should be examined by a physician prior to plasmapheresis (Tr. 2764*). He did not qualify his opinion based on the particular plasma by-product. The FDA regulations required that only first time donors of Source Plasma (Human) be examined by a doctor. 21 C.F.R. 640.63. There was no FDA regulation requiring examination of a first time donor of Fresh Human Serum. Only one of the eleven counts against petitioner, however, involved adulterated serum (Count 15). The government charged that the serum was adulterated not merely because it was not manufactured in compliance with good manufacturing practice but also because it was contaminated by hepatitis. The evidence bore out the hepatitis charge (Tr. 2408-2414, 2439). Moreover, aside from the medical examination issue, there were other bad manufacturing practices in association with the serum sample, notably the method of pooling serum samples in such a way that hepatitis could result (Tr. 2443-2450*, 2477-2484*).

then instructed the jury that, in assessing whether defendants violated the good manufacturing practice standard of the Federal Food, Drug, and Cosmetic Act, they could consider "the Federal Regulations, the expert testimony and * * * all the evidence in the case * * *" (Tr. 4189-4200*).

The jury convicted petitioner on all eleven counts and the district court sentenced him to two two-year sentences and nine one-year sentences, all to run concurrently (Pet. App. 2a). On appeal, the court of appeals noted that petitioner's sole ground for appeal —an objection to Dr. Gibson's testimony—concerned only some of the counts, and that the convictions under the remaining counts were unchallenged (*ibid.*). It affirmed the convictions on the challenged counts, concluding that the district court's admission of expert opinion testimony did not constitute reversible error (Pet. App. 3a).

3. The decision of the court of appeals is correct, raises no novel issue, and does not conflict with any decision of this Court or of any court of appeals. Accordingly, the case does not warrant further review.

Dr. Gibson described the plasma collection process, the health dangers to the plasma donor and subsequent recipients of plasma products, and methods that, in his opinion, could minimize those dangers. That testimony was surely of assistance to the jurors in determining if defendants' plasmapheresis enterprise was operated safely. The testimony gave tangible meaning to the FDA regulations. Admitting it

was consistent with Rule 702, Fed. R. Evid., with invites expert testimony if it will assist the jury to understand a contested issue. This Court has consistently ruled that "the District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true in the case of expert testimony." *Hamling* v. *United States*, 418 U.S. 87, 108 (1974). Under the circumstances, the court of appeals correctly concluded that the district court's decision to admit Dr. Gibson's testimony hardly could be veiwed as an abuse of its discretion constituting manifest error (Pet. App. 3a).

Petitioner's sole basis for challenging the rulings of both courts below is a novel and unfounded reading of Rule 704, Fed. R. Evid. That rule permits opinion testimony, even where it embraces an ultimate issue to be decided by the jury, provided that the expert does not "substitute for the court in charging the jury regarding the applicable law." *E.g.*, *United States* v. *Milton*, 555 F.2d 1198, 1203 (5th Cir. 1977). Dr. Gibson's testimony neither referred to the FDA regulations nor used the phrase "good manufacturing practice." It is therefore difficult to conceive how the jurors could have viewed the expert opinion testimony as instructions as to the law. The court left to the jury determinations of what was good manufacturing practice in the plasmapheresis industry and whether defendants met that standard. For assistance in making those determinations, the jury was permitted to consider the FDA regulations, the expert testimony, and all the evidence. Those instructions in effect

informed the jury that Dr. Gibson's opinion of appropriate industrial methods was not necessarily the legal standard of good manufacturing practice. This was the appropriate course in dealing with regulations and expert testimony in cases raising good manufacturing practice issues. *See, e.g., United States* v. *Dianovin Pharmaceuticals, Inc.*, 342 F. Supp. 724, 728 (D.P.R. 1972), aff'd, 475 F.2d 100 (1st Cir.), cert. denied 414 U.S. 830 (1973).[a]

[a] *Marx & Co., Inc. v. Diners' Club, Inc.*, 550 F.2d 505 (2d Cir.), cert. denied, 434 U.S. 861 (1977) does not support petitioner's conclusion that Dr. Gibson's testimony should be stricken under Rule 704, Fed.R.Evid. (Pet. 12-14). To the contrary, the court in *Marx*, while striking testimony of a witness which purported to give the definitive interpretation of a contract, observed that testimony concerning the ordinary practices of an industry is admissible "to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry." *Id.* at 509. Dr. Gibson's testimony in the present case gave the jury a better factual understanding of the risks of plasmapheresis and the practices of that industry without instructing the jury on the legal standard of care.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

WADE H. MCCREE, JR.
Solicitor General

JOHN H. SHENEFIELD
Assistant Attorney General

BARRY GROSSMAN
J. PATRICK GLYNN
WILLIAM D. COSTON
Attorneys

RICHARD M. COOPER
Chief Counsel

ROBERT P. BRADY
Attorney
Food and Drug Administration

FEBRUARY 1979

☆ U. S. GOVERNMENT PRINTING OFFICE: 1979 286100 303